
TRAINING AND COMMUNICATIONS

SUBMITTING ISSUES/DOCUMENTS TO THE OFFICE OF THE CHIEF COUNSEL FOR LEGAL REVIEW, COMMENT OR CLEARANCE

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Attachment A - CDER "OGC Tracking Information" Form

PURPOSE To establish the policies and procedures by which documents and issues are to be forwarded from the Center for Drug Evaluation and Research (CDER) to the Office of the Chief Counsel (OGC) for review, comment or clearance.

BACKGROUND

- Center staff routinely seek both informal and formal advice, and request clearance of documents, from OGC.
 - Because of the volume of requests, and the historical limitations on OGC resources, it has become necessary to identify CDER's work priorities so that OGC can respond to CDER requests more efficiently in the order in which they are needed as resources permit.
 - Accordingly, the Center is establishing this guide to track and prioritize requests for OGC advice and clearance.
 - This guide does not apply to informal requests for advice conveyed by telephone, E-mail or face-to-face that can be answered immediately and do not involve legal research or document review.
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DEFINITIONS

- **Concurrent Clearance** is clearance from OGC staff personnel.
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- **Final Clearance** is clearance from OGC management or their designee.
- **CDER/OGC Coordinator** is the Associate Director for Policy.
- **High Priority:**
 1. response from OGC is needed within 30 days of the initial request; or,
 2. the due date of the request is directly linked to a statutory or regulatory time frame; or,
 3. OGC's response will directly affect the way in which the Center will respond to a pending application.
- **Medium Priority:** response from OGC is needed within 90 days of the initial request date;
- **Low Priority:**
 1. the due date of the request is not dependent on a statutory or regulatory time frame; or,
 2. response from OGC is needed within 180 days of the initial request.

POLICY

- All documents sent to OGC for comment, review, or clearance, including any document going to the Federal Register and any response to a citizen's petition or suitability petition, should be forwarded to OGC accompanied by an "OGC Tracking Information Form" (see Attachment A).
- Requests for legal advice or opinions that cannot be answered immediately by phone and that require research by OGC also should be accompanied by an OGC Tracking Information Form.
- The form will enable the CDER/OGC Coordinator to enter information into a COMIS database that has been established to track CDER workload in OGC.

RESPONSIBILITIES AND PROCEDURES

- **Originators of requests:**
 1. Complete Part I of the OGC Tracking Information form (see Attachment A). [NOTE: This form is available electronically on the common shared drive, i.e., x:\ocd\form\ogctrack].

2. Obtain Division or Office level concurrence.
3. Forward the completed form with the material to be reviewed and any pertinent background material to OGC.
4. Forward a copy of the form and the material to the CDER/OGC Coordinator.

- **CDER/OGC Center Coordinator :**

1. Enter the appropriate information into the COMIS tracking system.
2. Meet periodically with OGC to discuss and adjust Center priorities for OGC work. The proposed “Action Due Date” will be modified as necessary through coordination and agreements between OGC and CDER based on priority levels.
3. Maintain the OGC Tracking System and provide periodic reports to CDER and OGC staff.
4. Prioritize the top ten items for OGC review on a monthly basis.

- **OGC:**

1. Consult and revise target due date as appropriate.
 2. Review the document and comment or clear it or respond to the request for advice.
 3. Complete Part II of the OGC Tracking Information form
 4. Enter the action and completion date into the COMIS tracking system.
 5. Forward the completed response to the originator.
 6. Forward a copy of the form to the CDER/OGC Coordinator.
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EFFECTIVE DATE

This guide is effective upon date of publication.

**CENTER FOR DRUG EVALUATION AND RESEARCH
OGC TRACKING INFORMATION FORM**

PLEASE SUBMIT A COPY OF ALL REQUESTS TO THE ASSOCIATE DIRECTOR FOR POLICY, HFD-5

PART I - TO BE COMPLETED BY REQUESTING OFFICE/DIVISION

PROJECT NAME:

DATE SENT TO OGC:

PROJECT DESCRIPTION: (Name of document or brief description of issue; include NDA/IND/ANDA number, if applicable)

DOCKET #/RES #/RIN# (for Policy Staff Use Only)

OFFICE/DIVISION: Originating request
HFD-

TARGET DUE DATE (MO/DA/YR):

PROGRAM CONTACT PERSON: (Telephone, Fax)

CDER POLICY STAFF CONTACT PERSON: (Telephone, Fax)

OGC CONTACT PERSON (if known):

PRIORITY (check one): ☐ HIGH ☐ MEDIUM ☐ LOW

TYPE OF PROJECT (check one):

☐ FR NOTICE (check appropriate designation):☐ ADVANCED NOTICE OF PROPOSED RULE MAKING☐ PROPOSED RULE☐ FINAL RULE☐ INTERIM RULE☐ NOTICE OF MEETING☐ FINAL ORDER☐ DEBARMENT ORDER☐ NOTICE OF OPPORTUNITY FOR HEARING☐ ICH DOCUMENT (CYCLE# ____; STEP# ____)☐ NOTICE OF HEARING☐ CITIZEN'S PETITION☐ ANDA SUITABILITY PETITION☐ QUESTION/OPINION (Any request for advice, review or concurrence other than petitions or Federal Register notices)☐ PROPOSED ENFORCEMENT ACTION☐ OTHER: _____ (e.g., guideline)

REQUESTED ACTION (check one):

☐ CONCURRENT CLEARANCE (review by OGC staff)☐ FINAL CLEARANCE (review by A.Wion or M.Porter or designee)☐ PROVIDE COMMENTS☐ REVIEW FOR MEETING (MEETING TOPIC: _____; DATE _____)☐ OTHER: _____

OFFICE/DIVISION DIRECTOR'S SIGNATURE:

PART II - TO BE COMPLETED BY OGC

DATE RECEIVED BY OGC:

DATE COMPLETED:

OGC CONTACT PERSON:

ACTION BY OGC:

☐ DOCUMENT CLEARED☐ DOCUMENT DENIED CLEARANCE☐ COMMENTS PROVIDED☐ OTHER: _____

OGC SIGNATURE:

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